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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/788,666	02/27/2004	Dale B. Schenk	15270J-004746US	3617

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EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/788,666

Applicant(s)

SCHENK, DALE B.

Examiner

Christopher J Nichols, Ph.D.

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,38,54-60,62-65,67-72,74-82,85-89 and 91-97 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1,38,54-60,62-65, 67-72,74-82,85-89 and 91-97 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Status of Application, Amendments, and/or Claims*

1. The preliminary amendment filed 16 August 2004 has been received and entered in full.

### *Election/Restrictions*

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claim 1, drawn to a **method** of preventing or treating a disease characterized by amyloid deposit in a patient comprising administering an effective dosage of an antibody that specifically binds to the amyloid deposit or a component thereof to the patient, classified in class 424, subclass 130.1, for example.
  - II. Claim 38, drawn to a **method** of preventing or treating Alzheimer's disease comprising administering an effective dosage of a polypeptide comprising an active fragment of A $\beta$  that induces an immune response to A $\beta$  in the patient, classified in class 424, subclass 187.1, for example.
  - III. Claims 54-55, drawn to a **method** of screening an antibody to A $\beta$  or an active fragment for use in treatment of Alzheimer's disease comprising use of a transgenic animal disposed to develop characteristics of Alzheimer's disease, classified in class 800, subclass 3, for example.
  - IV. Claims 56-60, 62-65, 67-72, 74, 76-82, 85-89, and 91-92, drawn to **methods** for effecting rapid improvement of cognition, treating cognitive symptoms, reducing disease progression comprising administering of an anti-A $\beta$  antibody, classified in class 424, subclass 130.1, for example.

V. Claims 75 and 93-97, drawn to **use (method)** of an anti-A $\beta$  antibody to prepare a medicament, classified in class 424, subclass 130.1, for example.

3. The inventions are distinct, each from the other because of the following reasons:

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I, II, III, IV, and V are directed to methods that are distinct both physically and functionally, and are not required one for the other.

5. Invention I requires search and consideration of passive immunization for preventing or treating a disease characterized by amyloid deposit, which is not required by Inventions III, III, IV, and V.

6. Invention II requires search and consideration of active immunization against A $\beta$ , which is not required by Inventions I, III, IV, and V.

7. Invention III requires search and consideration of screening potentially therapeutic agents using a transgenic animal, which is not required by Inventions I, II, IV, and V.

8. Invention IV requires search and consideration of passive immunization to treat cognition deficits, which is not required by Inventions I, II, III, and V.

9. Invention V requires search and consideration of manufacture of medicaments, which is not required by Inventions I, II, III, and IV.

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10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN

January 11, 2005

A handwritten signature in black ink, appearing to read "Nichols", with a large, stylized initial "C" on the left.